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| 09/853,467      | 05/11/2001  | Terry Lee Bray       | 30705-68918         | 6692             |

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EXAMINER

SONG, MATTHEW J

| ART UNIT | PAPER NUMBER |
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1765

DATE MAILED: 08/26/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/853,467

Applicant(s)

BRAY, TERRY LEE

Examiner

Matthew J Song

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 and 14-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 May 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-5 and 14-18, drawn to an apparatus, classified in class 117, subclass 200.
  - II. Claims 6-13 are drawn to a method, classified in class 117, subclass 70.
2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process, such as one where the container, device and solutions are not sealed.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Barbara Gibbs on 8/15/2002 a provisional election was made without traverse to prosecute the invention of I, claims 1-5 and 14-18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-13 are withdrawn

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from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

*Claim Rejections - 35 USC § 112*

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 21 and 23 recites the limitation "the crystal growth solution" in line 2. There is insufficient antecedent basis for this limitation in the claim, likewise for claim 23.

*Claim Rejections - 35 USC § 102*

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Heilig et al (US 5,266,284).

Heilig et al discloses a means of which the direction and amount of diffusion can be controlled by the degree of overlap of a gap and reservoirs, where three housing parts **106**, **102**, **112** with **112** being rotatably disposed with respect to a center part **102**. Heilig et al also discloses a protein solution **107** is situated in a glass cylinder **105** (col 4, ln 30-68). Heilig et al also discloses two recesses **96**, this reads on applicant's discrete channel, are situated in a wall of the center part which borders on a rotating part **112**, this reads on applicant's selection unit, two

reservoirs **130,132** are disposed in indentations inside the rotating part **112** and a component **122**, this reads on applicant's cover (Fig 14a). Heilig et al also discloses a sealing washer **92** is arranged between the rotating and the center part and the washer has recesses **93** which corresponds to those of **96** in the wall of the center part. Heilig et al also discloses for the crystallization phase, the rotating part is rotated so far the one of the reservoirs comes to be situated completely or partially over the recesses **96** and as a result diffusion can take place from or to a drop of protein solution **107** (col 5, ln 1-55 and Figs 14-17).

Referring to claim 14, Heilig et al discloses reservoirs **130** and **132**, a recess **96**, this reads on applicant's channel unit, and a rotating part **112**, this reads on applicant's selection unit with a opening (Figs 14-17) and the rotating part is rotated so far the one of the reservoirs comes to be situated completely or partially over the recesses **96**. Heilig et al is silent to the opening is large enough not to control the rate of vapor diffusion. It is inherent to the invention by Heilig et al to have an opening large enough not to control the rate of vapor diffusion because opening is as large as the reservoir opening (Fig 14b), therefore can not control the rate of vapor diffusion.

Referring to claim 15, Heilig et al discloses a cover, **122** (Fig 14a).

Referring to claim 16, Heilig et al is silent to the channel unit comprises an opening large enough not to control the rate of vapor diffusion. It is inherent to the invention taught by Heilig et al to have an opening large enough not to control the rate of vapor diffusion because the opening is as large as the reservoir opening, therefore can not control the rate of vapor diffusion (Fig 14b).

Referring to claim 17, Heilig et al discloses a sealing washer **92**.

Referring to claim 18, Heilig et al discloses the extent of diffusion can be controlled by the degree of overlap and the rotating part is rotated so far the one of the reservoirs comes to be situated completely or partially over the recesses, this reads on applicant's actively controlled channel unit.

8. Claims 19-22, and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al (US 6,039,804).

Kim et al discloses a crystallization unit **26** includes a central reservoir **28**, four diffusion channels **30** and four drop chambers **32**, where each drop chamber is connected to central reservoir **28** by one diffusion channel **30**. Kim et al also discloses a cover slip **46** is round and can be constructed from any optically transparent material. Kim also discloses in operation a liquid solvent is placed in central reservoir **28** and a drop of a solution containing the substance to be crystallized is placed on lower surface **40** of the drop chamber or a hanging drop can be achieved by applying a drop of solution containing the substance to be crystallized to a cover slip **46**, where the cover slip is supported by a shoulder **44** and once a drop of the solution containing the substance to be crystallized. Kim et al also discloses once a drop of the solution containing substance is placed within one ore more drop chambers, the drop chambers can be sealed by applying a sealant, preferably a transparent, adhesive tape (col 3, ln 50-67 and col 4, ln 15-67). Kim et al also discloses since each drop chamber within the crystallization unit is linked to the central reservoir by its own diffusion channel, vapor diffusion between the central reservoir and any one of the four drop chambers can be terminated by deposition of a vapor-impermeable substance in the diffusion channel, this reads on applicant's actively control channel size (col 5,

In 1-25). In a second embodiment, Kim et al discloses a crystallization a central reservoir **28'** is divided into four equal sections **58** by dividers **60** and each reservoir section **58** is connected to a drop chamber **32'** by a diffusion channel **30'** (col 6, ln 5-55). Kim et al also discloses a drop of solution of a substance to be crystallized that is identical to the drop of solution in every other drop chamber **32'**, except that none of the drops have the same pH and the pH of the reservoir of solvent in each central reservoir section **58** would be the same as the pH of the drop of solution in the to be crystallized in the drop chamber **32'** (col 7, ln 1-30).

Referring to claim 19, Kim et al discloses a central reservoir **28**, four diffusion channels **30**, this reads on applicant's device having defined therein discrete diffusion pathways, a cover slip **46** and a sealant, preferably a transparent, adhesive tape.

Referring to claim 20, Kim et al discloses diffusion channels **30**.

Referring to claim 21 as interpreted by the examiner, Kim et al discloses a reservoir divided into four sections and four diffusion channels.

Referring to claim 22, Kim et al discloses terminating vapor diffusion between the central reservoir and any one of the four drop chambers by depositing a vapor-impermeable substance in the diffusion channel, this reads on applicant's actively control the channel size.

Referring to claim 24, Kim et al discloses optically transparent cover slip **46**.

Referring to claim 25, Kim et al discloses a cover slip **46**.

Referring to claim 26, Kim et al discloses a transparent tape, this reads on applicant's optically clear tape.

Referring to claim 27, Kim et al discloses cover slip is supported by shoulder **44**, this reads on applicant's seal is configured to be removably secured to the device.

*Claim Rejections - 35 USC § 103*

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-4, 19-22 and 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (US 6,039,804) in view of Knittel et al (US 3,972,689).

Kim et al discloses all of the limitations of claim 1, as discussed previously in claim 19, except a device having discrete diffusion pathways, wherein the pathways control the vapor diffusion rate between a crystal growth solution and a reservoir solution.

In a method of vapor growing crystals, Knittel teaches conductance limiting and diffusion limiting channels, this reads on applicant's discrete diffusion pathways wherein the pathways control the vapor diffusion rate, which provide the only pathway between a sample source and a growing crystal. Knittel also teaches the channels can take many forms, such as several capillary tubes or fine holes drilled through a plug. Knittel also teaches restricting along the path of the source and the growing crystal. Knittel also discloses the vapor growth method produces crystals with improved quality and allows improved stoichiometric control (Fig 1 and col 1, ln 15-50 and col 2, ln 5-40).



It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Kim et al with Knittel's device with discrete diffusion pathways, wherein vapor diffusion rate is controlled because an increase in crystal size results from restricting vapor diffusion and crystals of improved quality are produced.

Referring to claim 2, the combination of Kim et al and Knittel teaches several capillary tubes.

Referring to claim 3, the combination of Kim et al and Knittel teaches several capillary tubes and a central reservoir with four sections 58, where each section can have a different pH, this reads on applicant's two different reservoir solutions.

Referring to claim 4, the combination of Kim et al and Knittel teaches terminating vapor diffusion between the central reservoir and any one of the four drop chambers by depositing a vapor-impermeable substance in the diffusion channel, this reads on applicant's actively control the channel size.

Referring to claim 19, the combination of Kim et al and Knittel teaches a central reservoir 28, diffusion limiting channels, a cover slip 46 and a sealant, preferably a transparent, adhesive tape.

Referring to claim 20, the combination of Kim et al and Knittel teaches several capillary tubes, this reads on applicant's discrete channels.

Referring to claim 21 as interpreted by the examiner, the combination of Kim et al and Knittel teaches a reservoir divided into four equal sections and a plurality of capillary tubes.

Referring to claim 22, the combination of Kim et al and Knittel teaches terminating vapor diffusion between the central reservoir and any one of the four drop chambers by depositing a

vapor-impermeable substance in the diffusion channel, this reads on applicant's actively control the channel size.

Referring to claim 24, the combination of Kim et al and Knittel teaches optically transparent cover slip **46**.

Referring to claim 25, the combination of Kim et al and Knittel teaches a cover slip **46**.

Referring to claim 26, the combination of Kim et al and Knittel teaches a transparent tape, this reads on applicant's optically clear tape.

Referring to claim 27, the combination of Kim et al and Knittel teaches cover slip is supported by shoulder **44**, this reads on applicant's seal is configured to be removably secured to the device.

Referring to claim 28, the combination of Kim et al and Knittel is silent to the device is configured to be removably secured to the container. It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the invention taught by the combination of Kim et al and Knittel by configuring the device to be removably secured to the container because performing maintenance on the device is easier. (MPEP 2144.04 C and In Re Dulberg, 129 USPQ 348)

Referring to claim 29, the combination of Kim et al and Knittel is silent to the device is configured to be removably secured to a container holding. It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the invention taught by the combination of Kim et al and Knittel by configuring the device to be removably secured to the container because performing maintenance on the device is easier. (MPEP 2144.04 C and In Re Dulberg, 129 USPQ 348)

11. Claim 5 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (US 6,039,804) in view of Knittel et al (US 3,972,689) as applied to claims 1-4 and 19-22 above, and further in view of Roorda et al (US 5,972,369).

The combination of Kim et al and Knittel teaches all of the limitations of claim 5, except the device is made of material porous to a vapor moving between the crystal growth solution and the reservoir solution.

In a diffusional delivery system, Roorda et al teaches a capillary channel filled with a loosely crosslinked, highly swollen, but immobilized gel through which diffusion of a beneficial agent takes place to prevent viscous flow of a liquid through the capillary channel, this reads on applicant's porous material (col 8, ln 1-35 and col 7, ln 1-20 and col 6, ln 40-65).

It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the combination of Kim et al and Knittel with Roorda et al's capillary channel filled with gel to prevent viscous flow of a liquid through the capillary channel.

Referring to claim 23 as interpreted by the examiner, the combination of Kim et al, Knittel and Roorda et al teaches several capillary channel filled with a porous material, this reads on applicant's device made of a porous material.

### *Conclusion*

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12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kent (US 4,452,775) teaches "pores" or channels, of such size and tortuosity as to permit the passage by diffusion at a controlled rate of macromolecular active agents (col 2, ln 25-65).

Carter (US 5,419,278) teaches a sitting drop method of vapor equilibration, where the presence of rib members and a cover slip form partial boundaries to vapor diffusion and there are deliberate restrictions in the vapor communication between a protein droplet and a reservoir, which slows the rate of equilibration and results in an increase in the size of resulting crystals. (col 8, ln 45-67 and Fig 3b).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Song whose telephone number is 703-305-4953

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Benjamin L Utech can be reached on 703-308-3868. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Matthew J Song  
Examiner  
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ROBERT KUNEMUND  
PRIMARY EXAMINER